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APPLICATION NO. 021839-037	FILING DATE 05/16/97	FIRST NAMED INVENTOR HARRISON	ATTORNEY DOCKET NO. 880475-205
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EXAMINER PHAM, M

ART UNIT 1641	PAPER NUMBER
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DATE MAILED: 03/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/858,087

Applicant(s)

HARRISON ET AL.

Examiner

Minh-Quan K. Pham, Ph.D.

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17, 19-31 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 17, 19-21, 27-31 and 35-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 1997 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

The amendment and petition to correct inventorship filed January 24, 2001, has been entered as Paper Nos. 21 and 22, respectively.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2001, has been entered.

Petition to Correct Inventorship

The petition to correct inventorship under 37 C.F.R. § 1.48(b) filed January 24, 2000, has been considered. The petition is granted. In accordance with petitioner's request, Per Anderson will be deleted as an inventor.

Claim Status

Claims 16-17, 19-31 and 35-39 are pending. Claims 17, 19-21, 27-31 and 35-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and species. Claims 18 is cancelled in Paper No. 21. Claims 16 and 22-26 are examined herein.

Art Unit: 1641

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Correction to the drawings as set forth in the Office action mailed February 19, 1999 (Paper No. 10) is required.

Double Patenting

Claims 16, 22-26 are provisionally rejected under the judicially created doctrine of double patenting over claims 16 and 22-26 of copending Application No. 09/080,546. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method of observing the effect of one or more candidate compounds on cells by flowing the compound and the cells into a microchannel and detecting the effect.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Objections

Art Unit: 1641

Claim 16 is objected to because of the following informalities: "a" in line 3 after "comprising" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection under 35 USC § 112 is withdrawn in light of claim amendment presented in Paper No. 21.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Pat. 5,942,443). The rejection is withdrawn in light of claim amendment presented in Paper No. 21.

NEW REJECTION

Claim 16 is rejected under 35 U.S.C. 102(a) as being anticipated by Li et al. (April 15, 1997), *Analytical Chemistry*, 69:1564-1568.

Li et al. disclose a microfluidic system for study of cells on a chip. Specifically Li et al. studied the effect of SDS on erythrocyte cells at a T-junction (see page 1567-1568, Lysis of Canine Erythrocytes, especially page 1568 first full paragraph; and Figure 5). Therefore Li et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Parce et al. (US Pat. 5,942,443) in view of Tracey et al. (reference of record on PTO-1449). The rejection is withdrawn in light of claim amendment presented in Paper No. 21.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US Pat. 5,942,443) in view of Tracey et al. (reference of record on PTO-1449) as applied to claim 22 above, and further in view of Wilding et al. ((reference of record on PTO-1449). The rejection is withdrawn in light of claim amendment presented in Paper No. 21.

NEW REJECTION

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (April 15, 1997), *Analytical Chemistry*, 69:1564-1568, in view of Tracey et al. (1995), *IEEE Transactions of Biomedical Engineering*, 42(8):751-761 (reference of record on PTO-1449).

See above for the disclosure of Li et al.

Li et al., however, differ from the claimed invention because they did not show that the cells are lymphocytes.

Art Unit: 1641

Tracey et al. disclose micro-machined devices in an analogous art for the purpose of showing devices which may be used in blood cell studies, and specifically shows the use of red blood cells and suggests the extension of the technology to leukocyte (lymphocytes are a subset of leukocytes) cell analysis (see abstract).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to use lymphocytes in the apparatus and method of Li et al. because erythrocytes and leukocytes can be assayed in microfluidic devices with high reproducibility and precision, as taught by Tracey et al. (see page 759, Conclusions).

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (April 15, 1997), *Analytical Chemistry*, 69:1564-1568, in view of Tracey et al. (1995), *IEEE Transactions on Biomedical Engineering*, 42(8):751-761 (a reference of record on PTO-1449), as applied to claim 22 above, and further in view of Wilding et al. (1994), *Clinical Chemistry*, 40(1):43-47 (reference of record on PTO-1449).

See above for the disclosure of Parce et al. in view of Tracey et al.

Li et al. in view of Tracey et al., however, differ from the claimed invention because they do not disclose that the flow paths are coated.

Wilding et al. disclose albumin-coated microchannels for the flow of biological fluids (see page 44, second column, second paragraph).

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to coat the microchannels of Li et al., as modified by Tracey et al., in order to prevent the attachment of other proteins to the wall of the channel, as taught by Wilding et al.

Art Unit: 1641

This method of preventing the attachment of proteins to the wall of channels is well known in the art and generally referred to as blocking.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham, Ph.D., whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.
March 15, 2001



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641